

Docket No.: CHR-004 (PATENT)

### IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of: Norman R. Wainwright et al.

Application No.: 10/803,177

cation No.: 10/803,1//

Filed: March 17, 2004

For: METHODS AND COMPOSITIONS FOR

THE DETECTION OF MICROBIAL

**CONTAMINANTS** 

Confirmation No.: 4155

Art Unit: 1744

Examiner: N. A. Bowers

#### SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT (SIDS)

MS Amendment Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

Dear Sir:

Pursuant to 37 CFR 1.56, 1.97 and 1.98, the attention of the Patent and Trademark Office is hereby directed to the references listed on the attached PTO/SB/08. It is respectfully requested that the information be expressly considered during the prosecution of this application, and that the references be made of record therein and appear among the "References Cited" on any patent to issue therefrom. The publication for corresponding International Patent Application PCT/US04/08013 is cited under B5. The published Search Report for this International Patent Application was previously cited to the Office under C72.

This Information Disclosure Statement is filed more than three months after the U.S. filing date, OR more than three months after the date of entry of the national stage of a PCT application, AND after the mailing date of the first Office Action on the merits, whichever occurs first, but before the mailing date of a Final Office Action or Notice of Allowance (37 CFR 1.97(c)).

Application No.: 10/803,177 2 Docket No.: CHR-004

In accordance with 37 CFR 1.98(a)(2)(ii), Applicant has not submitted copies of U.S. patents and U.S. patent applications. Applicant submits herewith copies of foreign patents and non-patent literature in accordance with 37 CFR 1.98(a)(2).

In accordance with 37 CFR 1.97(g), the filing of this Information Disclosure Statement shall not be construed to mean that a search has been made or that no other material information as defined in 37 CFR 1.56(a) exists. In accordance with 37 CFR 1.97(h), the filing of this Information Disclosure Statement shall not be construed to be an admission that any patent, publication or other information referred to therein is "prior art" for this invention unless specifically designated as such.

It is submitted that the Information Disclosure Statement is in compliance with 37 CFR 1.98 and the Examiner is respectfully requested to consider the listed references.

Our check including the \$180.00 fee set forth in 37 CFR 1.17(p) is enclosed. The Director is hereby authorized to charge any deficiency in the fees filed, asserted to be filed or which should have been filed herewith (or with any paper hereafter filed in this application by this firm) to our Deposit Account No. 07-1700, under Order No. CHR-004. A duplicate copy of this paper is enclosed.

Dated: February 5, 2007

Respectfully submitted,
Rondoll D. Moin Roy No. 58,312

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PTO/SB/08A/B (09-06) Approved for use through 03/31/2007. OMB 0651-0031 U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Substitute for form 1449/PTO

Sheet

## INFORMATION DISCLOSURE STATEMENT BY APPLICANT

FORMATION DISCLOSURE  FATEMENT BY APPLICANT  (Use as many sheets as necessary)			Complete if Known		
			Application Number	10/803,177	
			Filing Date	March 17, 2004	
			First Named Inventor	Norman R. Wainwright	
			Art Unit	1744	
			Examiner Name	N. A. Bowers	
1	of	1	Attorney Docket Number	CHR-004	

	U.S. PATENT DOCUMENTS				
Examiner Initials*	Cite No.1	Document Number  Number-Kind Code <sup>2</sup> ( if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant
Irikidis	ļ	, , ,			Figures Appear
	A1*	US-20030104501-A1	06-05-2003	Jordan et al.	
	A2*	US-20060216780-A1	09-28-2006	Wainwright et al.	
	A3*	US-20060183181-A1	08-17-2006	Wainwright et al.	

		FOREI	GN PATENT	DOCUMENTS		
	Cite	Foreign Patent Document	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	
	No.1	Country Code <sup>3</sup> -Number <sup>4</sup> -Kind Code <sup>5</sup> (if known)				T⁵
	В1	JP-61093958	05-12-1986	Daicel Chem	Abstract only in English	×
	B2	GB-A-2080524	02-03-1982	Mallinckrodt, Inc.		
	В3	WO-83/02123	06-23-1983	Soderhall		
	B4	WO-99/19355	04-22-1999	Jordan et al.		
	B5	WO-05/10207	02-03-2005	Wainwright et al.		
	B6	WO-06/76617 A3	07-20-2006	Wainwright et al.		

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not \*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 809. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. \* CITE NO.: Those application(s) which are marked with an single asterisk (\*) next to the Cite No. are not supplied (under 37 CFR 1.98(a)(2)(iii)) because that application was filed after June 30, 2003 or is available in the IFW. 'Applicant's unique citation designation number (optional). <sup>2</sup> See Kinds Codes of USPTO Patent Documents at <a href="www.uspto.gov">www.uspto.gov</a> or MPEP 901.04. <sup>3</sup> Enter Office that issued the document, by the two-letter code (MPO Standard ST.3). <sup>4</sup> For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>5</sup> Kind of document by the appropriate symbols as indicated on the document under WPO Standard ST.16 if possible. <sup>6</sup> Applicant is to place a check mark here if English language Translation is attached.

		NON PATENT LITERATURE DOCUMENTS	
Examiner Initials	Cite No.1	Include name of the author ( in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T²
	C1	Coates, D.A., "Enhancement of the Sensitivity of the Limulus Assay for the Detection of Gram Negative Bacteria," (1977) Journal of Applied Bacteriology 42: 445-449.	
	C2	Inada et al., "A Silkworm Larvae Plasma Test for Detecting Peptidoglycan in Cerebrospinal Fluid is Useful for the Diagnosis of Bacterial Meningitis," (2003) Microbiology and Immunology, 47:(10): 701-707.	
	C3	Janda et al., "A Colorimetric Estimation of Lipopolysaccharides," (1970) Febs Letters 16: (4): 343-354.	
	C4	Maeda et al., "Chromogenic Assay Method of Lipopolysaccharide (LPS) for Evaluating Bacterial Standing Crop in Seawater," (1979) Journal of Applied Bacteriology 47: 175-182.	
	C5	Sigma Chemical Company E-Toxate Technical Bulletin (2000) No. 210: 1-4.	
	C6	Wiegel et al., "Determination of the Gram Type Using the Reaction Between Polymyxin B and Lipopolysaccarides of the Outer Cell Wall of Whole Bacteria," Journal of General Microbiology (1982) 28: 2261-2270.	
	C7	Charles River Laboratories, "LAL Products and Services" (2001).	
	C8	Prior, Richard B. Ed., (1990) "Clinical Applications of the Limulus Amebocyte Lysate Test" CRC Press, pp. 28-34.	

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

Applicant's unique citation designation number (optional). Applicant is to place a check mark here if English language Translation is attached.

Examiner	Date
Signature	Considered

PTO/SB/17 (07-06)

Approved for use through 01/31/2007. OMB 0651-0032 U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE Under the Paperwork Reduction Act of 1995, no person are required to respond to a collection of information unless it displays a valid OMB control number. Complete if Known Effective on 12/08/2004. Fees pursuant to the Consolidated Appropriations Act, 2005 (H.R. 4818). 10/803,177 Application Number TRANSMITTAL Filing Date March 17, 2004 Norman R. Wainwright First Named Inventor For FY 2005 Examiner Name N. A. Bowers Applicant claims small entity status. See 37 CFR 1.27 1744 Art Unit CHR-004 **TOTAL AMOUNT OF PAYMENT** Attorney Docket No. METHOD OF PAYMENT (check all that apply) x Check None Credit Card Money Order Other (please identify): x Deposit Account Deposit Account Number: 07-1700 Deposit Account Name: Goodwin Procter LLP For the above-identified deposit account, the Director is hereby authorized to: (check all that apply) Charge fee(s) indicated below, except for the filing fee Charge fee(s) indicated below Charge any additional fee(s) or underpayment of x Credit any overpayments fee(s) under 37 CFR 1.16 and 1.17 **FEE CALCULATION** 1. BASIC FILING, SEARCH, AND EXAMINATION FEES **EXAMINATION FEES SEARCH FEES FILING FEES** Small Entity **Small Entity Small Entity** Fee (\$) Fee (\$) Fees Paid (\$) **Application Type** Fee (\$) Fee (\$) Fee (\$) Fee (\$) 500 250 200 100 300 150 Utility 200 100 100 50 130 65 Design 300 160 80 Plant 200 100 150 Reissue 300 150 500 250 600 300 0 200 100 0 0 0 Provisional **Small Entity** 2. EXCESS CLAIM FEES Fee (\$) Fee (\$) Fee Description Each claim over 20 (including Reissues) 50 25 200 100 Each independent claim over 3 (including Reissues) Multiple dependent claims 360 180 Multiple Dependent Claims **Total Claims** Extra Claims Fee Paid (\$) Fee (\$) Fee Paid (\$) Fee (\$) HP = highest number of total claims paid for, if greater than 20. Indep. Claims Extra Claims Fee (\$) Fee Paid (\$) HP = highest number of independent claims paid for, if greater than 3. 3. APPLICATION SIZE FEE If the specification and drawings exceed 100 sheets of paper (excluding electronically filed sequence or computer listings under 37 CFR 1.52(e)), the application size fee due is \$250 (\$125 for small entity) for each additional 50 sheets or fraction thereof. See 35 U.S.C. 41(a)(1)(G) and 37 CFR 1.16(s). Fee Paid (\$) Number of each additional 50 or fraction thereof Fee (\$) Extra Sheets \_\_\_\_ (round up to a whole number) x - 100 <del>=</del> 4. OTHER FEE(S) Fees Paid (\$) Non-English Specification, \$130 fee (no small entity discount) Petition for Extension of Time Under 37 CFR 1.136(a) 120.00 Other (e.g., late filing surcharge): 180.00 1806 Submission of an Information Disclosure Statement SUBMITTED BY 58,312 Registration No 38,678 Telephone (617) 570-1299 Signature (Attorney/Agent) February 5, 2007 Duncan A. Greenhalgh Date Name (Print/Type)



PTO/SB/92 (09-06)

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Application No. (if known): 10/803,177

Attorney Docket No.: CHR-004

# Certificate of Mailing under 37 CFR 1.8

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	Date	

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